K130885

SIEMENS



MAY 17 2013

# Section 5 510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of Safe Medical Device Act 1990 and 21 CFR § 807.92.

**I. General Information**

| | |
|---|---|
| **Establishment** | Siemens Medical Solutions USA. Inc.<br>51 Valley Stream Parkway<br>Mail Code G01<br>Malvern, PA 19355, USA |
| **Registration Number** | 2240869 |
| **Date Prepared** | March 26, 2013 |
| **Manufacturer** | Siemens AG<br>Henkestrasse 127<br>D-91052 Erlangen, Germany |
| **Registration Number** | 8010024 |
| **Contact Person** | Ms. Kim Rendon<br>Sr. Manager, Regulatory Affairs/Clinical Affairs<br>Siemens Healthcare<br><br>Siemens Medical Solutions USA, Inc.<br>Customer Solutions Group<br>51 Valley Stream Parkway<br>Mail Code G01<br>Malvern, PA 19355, USA<br>Phone: (610) 448-1773<br>Fax: (610) 448-1787 |
| **Device Name** | Trade Names: MAGNETOM Avanto$^{fit}$<br>MAGNETOM Skyra$^{fit}$ |
| **Classification Name:** | Magnetic Resonance Diagnostic Device |
| **CFR Code:** | 21 CFR § 892.1000 |
| **Classification:** | Class II |

**Performance Standards** None established under Section 514, Subpart J of the Food, Drug and Cosmetic Act.

## II. Safety and Effectiveness Information Supporting Substantial Equivalence

### Intended Use

The MAGNETOM Avanto$^{fit}$ and the MAGNETOM Skyra$^{fit}$ systems are indicated for use as a magnetic resonance diagnostic device (MRDD) that produces transverse, sagittal, coronal and oblique cross sectional images, spectroscopic images and/or spectra, and that displays the internal structure and/or function of the head, body, or extremities.

Other physical parameters derived from the images and/or spectra may also be produced. Depending on the region of interest, contrast agents may be used. These images and/or spectra and the physical parameters derived from the images and/or spectra when interpreted by a trained physician yield information that may assist in diagnosis.

The MAGNETOM Avanto$^{fit}$ and the MAGNETOM Skyra$^{fit}$ MR systems may also be used for imaging during interventional procedures when performed with MR compatible devices such as in-room display and MR-safe biopsy needles.

### Device Description

MAGNETOM Avanto$^{fit}$ (1.5 T) and MAGNETOM Skyra$^{fit}$ (3 T) are similar to the previously cleared MAGNETOM Aera (1.5 T) and MAGNETOM Skyra (3 T) systems utilizing a superconducting magnet design. The open bore, whole body scanners are designed for increased patient comfort. They focus on ergonomics and usability to reduce complexity of the MR workflow.

The MAGNETOM Avanto$^{fit}$ and the MAGNETOM Skyra$^{fit}$ systems will be offered as an upgrade to the currently installed MAGNETOM Avanto and MAGENTOM Verio systems. The MAGNETOM Avanto$^{fit}$ will also be offered as ex-factory (new production).

### Substantial Equivalence

It is Siemens opinion that the upgraded MAGNETOM Avanto$^{fit}$ and Skyra$^{fit}$ systems are substantially equivalent to the following predicate devices:

| *Predicate Device Name* | *FDA Clearance Number* | *FDA Clearance Date* |
|---|---|---|
| Siemens MAGNETOM Area* (1.5T) | K101347 | October 1, 2010 |
| Siemens MAGNETOM Skyra* (3 T) | K101347 | October 1, 2010 |
| *With syngo® MR VA13A SW Update | K121434 | November 5, 2012 |
| Siemens MAGNETOM Avanto(1.5T) & MAGNETOM Verio System with syngo® MR B17 update | K082427 | November 7, 2008 |
| Siemens MAGNETOM Verio (3 T) MR System | K072237 | October 10, 2007 |

**General Safety and Effectiveness Concerns:**
The device labeling contains instructions for use and any necessary cautions and warnings, to provide for safe and effective use of the device.

Risk management is ensured via a risk analysis, which is used to identify potential hazards and mitigations. These potential hazards are controlled by software means, user instructions, verification of requirements and validation of the clinical workflow to ensure that the product meets its intended uses. To minimize electrical, mechanical and radiation hazards, SIEMENS adheres to recognized and established industry practice and relevant international standards.

Operation of the MAGNETOM Avanto$^{fit}$ (1.5T) and the MAGNETOM Skyra$^{fit}$ (3T) systems with syngo® MR VD13B software is substantially equivalent to the commercially available MAGNETOM Aera (1.5T) and MAGNETOM Skyra (3T) Systems with syngo® MR VD13A SW (K121434)

Additionally, as specified in the FDA guidance document "Guidance for the Submission Of Premarket Notifications for Magnetic Resonance Devices" (released Nov. 1998) the following measurements of performance and safety data have been performed following NEMA or equivalent IEC and ISO standards:

**Safety:**
- Maximum Static Field
- Rate of Change of Magnetic Field
- RF Power Deposition
- Acoustic Noise Levels

**Performance:**
- Specification Volume
- Signal to Noise
- Image Uniformity
- Geometric Distortion
- Slice Profile. Thickness and Gap
- High Contrast Spatial Resolution

The MAGNETOM Avanto$^{fit}$ and MAGNETOM Skyra$^{fit}$ will conform to the measurements of safety parameters to the international IEC, ISO and NEMA standards for safety issues with Magnetic Resonance Imaging Diagnostic Devices.

Furthermore performance measurements have been done on the predicate devices MAGNETOM Avanto and MAGNETOM Verio to show that the performance of the MAGNETOM Avanto$^{fit}$ and MAGNETOM Skyra$^{fit}$ with *syngo*® MR VD 13B Software is equivalent with respect to the predicate devices.

This will assure that the performance of these devices can be considered as safe and effective with respect to the currently available MAGNETOM Aera and MAGNETOM Skyra MR systems.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Siemens Medical Solutions USA, Inc.
% Ms. Christine Dunbar
Sr. Manager, Regulatory Affairs
757 A Arnold Drive
MARTINEZ CA 94553

May 17, 2013

Re: K130885
Trade/Device Name: MAGNETOM Avanto$^{fit}$ and MAGNETOM Skyra$^{fit}$
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic Resonance Diagnostic Device
Regulatory Class: II
Product Code: LNH
Dated: March 26, 2013
Received: March 29, 2013

Dear Ms. Dunbar:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Michael D. O'Hara for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

# Section 4 Indications for Use Statement

510(k) Number (if known) K130885

Device Names: **MAGNETOM Avanto$^{fit}$ and MAGNETOM Skyra$^{fit}$**

**Indications for Use:**

The MAGNETOM systems described above are indicated for use as a magnetic resonance diagnostic device (MRDD) that produces transverse, sagittal, coronal and oblique cross sectional images, spectroscopic images and/or spectra, and that displays the internal structure and/or function of the head, body, or extremities.

Other physical parameters derived from the images and/or spectra may also be produced. Depending on the region of interest, contrast agents may be used. These images and/or spectra and the physical parameters derived from the images and/or spectra when interpreted by a trained physician yield information that may assist in diagnosis.

The MAGNETOM systems described above may also be used for imaging during interventional procedures when performed with MR compatible devices such as in-room display and MR-safe biopsy needles.

| | | |
|---|---|---|
| Prescription Use X<br>(Per 21 CFR 801, Subpart D) | OR | Over-The-Counter Use____<br>(Per 21 CFR 801, Subpart C) |

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic and Radiological Health (OIR)

Michael D. O'Hara

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K130885

Page 1 of 1